

### **Remarks**

Claims 39-40, 42-44 and 46-60 are pending in the application. Claims 39-40, 42, 44 and 46 have been amended as shown above. The claims were amended to clarify the invention more fully. No new matter has been added by the amendments. New claims 47-60 have been inserted. Favorable reconsideration is respectfully requested in light of the above amendments and the following comments.

The Examiner rejected claims 39-46 under 35 U.S.C. 102(b) as being anticipated by Jang. The Examiner also rejected claims 39-46 under 35 U.S.C. 103(a) as being unpatentable over Jang. Applicants respectfully traverse these rejections.

### **35 U.S.C. § 102 Rejection**

The Examiner rejected claims 39-46 under 35 U.S.C. 102(b) as being anticipated by Jang (US 4,590,062). Jang teaches a controlled release formulation comprising:

- from 0.01 to 95% of a particulate biologically active agent smaller than 10 mesh, and
- from 5 to 99.9% of a controlled release compressible binder mixture (matrix) containing :
  - (a) from 0 to 99% of a fatty acid material or neutral lipid powder smaller than 20 mesh,
  - (b) from 0 to 99% of a wax powder smaller than 20 mesh with a melting point 50°-100°C,and
  - (c) from 1 to 100% of a hydrophobic carbohydrate polymer powder, e.g. ethyl cellulose, smaller than 20 mesh.

According to Jang, the biologically active agent is readily dispersed into the blended powders providing the matrix whereby the resultant formulation can be dry and direct compressed on a press to produce tablets.

Jang does not teach a solid shaped article, such as a tablet, comprising two distinct populations of beads in a weight ratio between 30 :70 and 70 :30, i.e. one population of biologically active agent coated beads and a population of cushioning beads wherein a wax is an essential cushioning component. Thus Jang does not anticipate the subject matter of amended claims 39 and 44 or any claim depending therefrom.

### **35 U.S.C. § 103 Rejection**

The Examiner rejected claims 39-46 under 35 U.S.C. 103(a) as being unpatentable over Jang.

The formulation disclosed by Jang belongs to the category of formulations which face a number of difficult problems when the particulate biologically active agent is coated, as explained in detail at page 3 of the present specification. Mainly, the coat is damaged during compression. The purpose of the present invention is therefore to prevent cracking of the coating during compacting. There is no hint or suggestion in Jang to solve this problem by the use of cushioning beads. Thus, the non-obviousness of the claimed subject matter is not supported by differences in the concentration of wax, but by the different physical structure of the formulation.

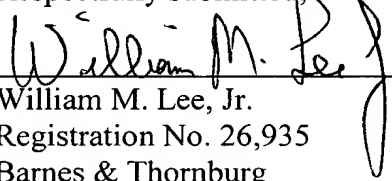
There is no suggestion in Jang of selecting wax as an essential cushioning component of such beads. Thus Jang does not make obvious the subject matter of amended claims 39 and 44 or any claim depending therefrom.

**Conclusion**

In view of the arguments presented therein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

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Respectfully submitted,

  
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